UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ANTHONY VELASCO, on behalf of himself and all others similarly situated, Plaintiff, vs. SEI PHARMACEUTICALS, INC., a Florida Corporation, and DOES 1-10, inclusive, Defendants.	CASE NO. 12cv1060-WQH-MDD ORDER

HAYES, Judge:

The matter before the Court is the Motion to Dismiss Plaintiff's First Amended Class Action Complaint, filed by Defendant SEI Pharmaceuticals, Inc. (ECF No. 22).

I. Background

On February 1, 2013, Plaintiff Anthony Velasco filed the First Amended Complaint, which is the operative pleading in this action. (ECF No. 20).

A. Allegations of the First Amended Complaint

Defendant manufactures, markets and sells MethylHex 4,2 (the "Product") as a supplement which it represents has the ability to provide an "elevated sense of well-being, improved mood, increased CLEAN energy, suppressed appetite and heightened focus," in addition to being "a powerful CNS stimulant, for added energy, increased clarity and a boost in physical performance, especially valuable to athletes during calorie restriction or when a high level of focus is needed." *Id.* ¶ 8. The Product lists 4-methylhexan-2-amine HCL, also known as dimethylamylamine or DMAA, as one of its ingredients. *Id.* ¶¶ 18, 19. The Product label claims that the DMAA in the

Product consisted of "Geranium Extract Leaves and Stem," when, in fact, the DMAA in the Product was synthetic and not extracted from geraniums. *Id.* ¶ 19. The Food and Drug Administration ("FDA") has sent a warning letter to Defendant stating, among other things, that synthetically-produced DMAA is not a "dietary ingredient" under the Dietary Supplement Health and Education Act of 1994 and, therefore, is not eligible to be used as an active ingredient in a dietary supplement. *Id.* ¶ 16. The FDA has received 42 adverse event reports on products containing DMAA, some including complaints of cardiac disorders, nervous system disorders, psychiatric disorders, and death. *Id.* ¶ 15.

Plaintiff purchased the Product in July or August of 2011 in reliance on Defendant's misrepresentations regarding the efficacy, safety and legality of the Product. *Id.* at ¶¶ 18, 22. But for Defendant's misrepresentations and material omissions, Plaintiff would not have purchased or paid as much for the Product. *Id.* ¶ 22. Plaintiff asserts the following three causes of action against Defendant: (1) false advertising in violation of California Business & Professions Code §17500; (2) unfair competition in violation of California Business & Professions Code §17200, *et seq.*; and (3) unfair competition and deceptive business practices in violation of California Civil Code §1770, *et seq*. Plaintiff purports to bring a class action on behalf of all persons who are citizens or residents of the United States of America who purchased the Product within the four years prior to the filing of the original complaint.

B. Motion to Dismiss

On February 12, 2013, Defendant filed the Motion to Dismiss Plaintiff's First Amended Class Action Complaint. (ECF No. 22). Defendant contends that "this case calls for factual and legal determinations that should be resolved by the responsible agency itself, the FDA, guided by its own technical expertise and policy objectives." *Id.* at 8. Defendant contends:

> The Court should defer to the 'primary jurisdiction' of the FDA, as the agency charged with protecting the public health and determining and remedying alleged non-compliance with federal regulations regarding dietary supplement labeling and marketing. Where, as here, the legislature has created a complex regulatory scheme enforced by an executive agency with expertise in the subject matter area and with the need for uniformity

> in application of such complex regulations, it is appropriate at the very least for the Court to decline to adjudicate the matter until the responsible administrative agency has considered the issues.

Id. Defendant contends that, pursuant to the primary jurisdiction doctrine, "this case should be dismissed with prejudice in deference to the FDA or, at a minimum, the case should be stayed pending referral of the 'regulatory' issues to the FDA." *Id*. at 9. Defendant alternatively contends that the class allegations should be dismissed or stricken because whether the class members read and relied on the statements on the Product's packaging is inherently an individual analysis and thus not one which provides a basis for a class action.

On March 5, 2013, Plaintiff filed an opposition to the Motion to Dismiss. (ECF No. 23). Plaintiff contends that all of Plaintiff's claims are grounded in California consumer protection statutes, and are actionable independent of any determinations delegated to the jurisdiction of the FDA. Plaintiff asserts that, a week prior to the filing of Plaintiff's original Complaint, the FDA issued a warning letter to Defendant demanding that Defendant immediately cease distribution of the Product. *See id*. at 10. Plaintiff contends that, "since the issues entailed here are not within the exclusive jurisdiction of the FDA, and the FDA has already substantially performed the regulatory functions Defendant alleges are exclusively within FDA jurisdiction, the Court need not invoke its discretionary authority to defer the matter to the FDA based on the primary jurisdiction doctrine." *Id*. at 5. Plaintiff contends that the putative class satisfies the commonality requirement because "once a named plaintiff establishes that he or she suffered injury in fact and lost money or property as a result of the unfair competition, no further individualized proof of injury or causation is required to impose restitution liability against the defendant in favor of absent class members." *Id*. at 20-21.

On March 11, 2013, Defendant filed a reply in support of the Motion to Dismiss. (ECF No. 25).

II. Standard of Review

Federal Rule of Civil Procedure 12(b)(6) permits dismissal for "failure to state

a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Federal Rule of Civil Procedure 8(a) provides that "[a] pleading that states a claim for relief must contain ... a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Dismissal under Rule 12(b)(6) is appropriate where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. *See Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990).

A plaintiff's "grounds" to relief must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting Fed. R. Civ. P. 8(a)(2)). When considering a motion to dismiss, a court must accept as true all "well-pleaded factual allegations." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). However, a court is not "required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). "In sum, for a complaint to survive a motion to dismiss, the non-conclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. U.S. Secret Service*, 572 F.3d 962, 969 (9th Cir. 2009) (quotations omitted).

Pursuant to Federal Rule of Civil Procedure 12(f), a "court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f).

III. Discussion

A. Primary Jurisdiction

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008) (citation omitted). "A court's invocation of the doctrine does not indicate that it lacks jurisdiction. Rather, the doctrine is a prudential one, under which a court determines that an otherwise cognizable claim implicates technical and policy

questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Id*. (citation omitted). "[T]he doctrine is not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit. Instead, it is to be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency, and if protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Id*. (quotations omitted). "When a district court determines that primary jurisdiction applies, it enables a referral of the issue to the relevant agency. In practice, this means that the court either stays proceedings or dismisses the case without prejudice, so that the parties may seek an administrative ruling. There is no formal transfer mechanism between the courts and the agency; rather, the parties are responsible for initiating administrative proceedings themselves." *Id*. at 1115 (quotation omitted).

On April 24, 2012, the FDA issued a Warning Letter to Defendant regarding the Product.[1] (ECF No. 6-2). The Warning Letter concludes:

> Failure to immediately cease distribution of your product MethylHex 4,2 and any other products you market that contain dimethylamylamine could result in enforcement action by [the] FDA without further notice. The Act provides for seizure of violative products and injunction against the manufacturers and distributors of violative products.
>
> We request that you advise us in writing, within 15 days of receipt of this letter, as to the specific steps that have been or will be taken to correct these violations, including any steps taken with respect to product currently in the marketplace.

Id. at 3.

Plaintiff contends that this letter is evidence that "the FDA has *already* acted" in this matter, and therefore dismissal or stay based upon the doctrine of primary

[1] Plaintiff's unopposed Request for Judicial Notice (ECF No. 6-1) of the Warning Letter is granted. *See Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994) (holding that a court may consider "documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading").

jurisdiction is not warranted. (ECF No. 23 at 18). Defendant contends that the Warning Letter is only evidence that the FDA has acted in "a preliminary manner," and the Warning Letter "specifically contemplates further FDA action and interaction between Defendant and the FDA, including, but not limited to, 'enforcement action by [the] FDA without further notice.'" (ECF No. 25 at 4).

Defendant asserts that it "no longer sells a product which contains DMAA," and it ceased selling the Product at issue with DMAA as an ingredient in May of 2012. *Id*. at 2. Accordingly, it appears Defendant concedes that it has complied with the FDA's request that Defendant "immediately cease distribution of your product MethylHex 4,2 and any other products you market that contain dimethylamylamine." (ECF No. 6-2 at 3). Defendant does not indicate that the FDA has taken any action since the April 24, 2012 Warning Letter, and Defendant does not provide evidence indicating that it is likely that the FDA will take any future action in this matter. Defendant has failed to identify an available procedure for "the parties [to] seek an administrative ruling" from the FDA in this matter if the Court were to stay or dismiss the case on the basis of primary jurisdiction. *Clark*, 523 F.3d at 1115. Based upon the current record, the Court declines to stay this action or dismiss the First Amended Complaint on the basis of primary jurisdiction.

B. Class Allegations

Defendant contends that the class allegations should be dismissed or stricken because whether the class members read and relied on the statements on the Product's packaging is an individual analysis and thus not one which provides a basis for a class action. The parties cite many cases addressing the issue of whether reliance may be presumed on a class-wide basis in a case such as this. (ECF No. 22 at 20-21; ECF No. 23 at 19-22; ECF No. 25 at 5-7). Each of these cases addressed this issue in the context of a motion for class certification pursuant to Federal Rule of Civil Procedure 23, rather than a motion to dismiss or strike pursuant to Federal Rule of Civil Procedure 12.

After review of the First Amended Complaint, the Court finds that Plaintiff has

alleged each of the elements necessary for class certification pursuant to Federal Rule of Civil Procedure 23. (ECF No. 20 at 7-9). The Court finds that, based upon the record in this case, issues related to class suitability are more appropriately reserved for a motion for class certification. *See Rosales v. FitFlop USA, LLC*, 882 F. Supp. 2d 1168, 1179 (S.D. Cal. 2012) ("Determining whether to certify a class is normally done through a motion for class certification under Rule 23.... The Court finds that class suitability issues are best resolved during a motion for class certification. As a result, so long as class action allegations address each of the elements of Rule 23, relate to the subject matter of the litigation, and are not redundant, immaterial, or impertinent, the court should find that the allegations are sufficient to survive a motion to strike.") (citations omitted); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1035 (N.D. Cal. 2009) ("The Court cannot determine on the pleadings whether a class-wide inference [of reliance] is appropriate in this case. Accordingly, defendant's motion to strike the class allegations is denied without prejudice to the Court considering the issue on a fully-briefed and supported motion concerning class certification."); *Clark v. State Farm Mut. Auto. Ins. Co.*, 231 F.R.D. 405, 407 (C.D. Cal. 2005) ("Defendant relies on cases addressing whether a class should be certified, not whether class action allegations in a complaint should be stricken. Defendant's motion is premature.... Viewing the complaint in the light most favorable to Plaintiff, the Court finds that Plaintiff's class allegations are sufficient to survive a motion to strike. Whether Plaintiff will be able to succeed on a motion for class certification, however, is an entirely separate matter to be decided at a later date."). The motion to dismiss or strike the class allegations is denied.

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IV. Conclusion

IT IS HEREBY ORDERED that the Motion to Dismiss Plaintiff's First Amended

Class Action Complaint is DENIED. (ECF No. 22).

DATED: June 5, 2013

WILLIAM Q. HAYES
United States District Judge